

this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration’s communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) **CONTENT.**—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) **ISSUANCE AND POSTING OF COMMUNICATION PLAN.**—

(1) **COMMUNICATION PLAN.**—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) **POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.**—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

SA 2126. Mr. REED submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled “Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates” (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled “Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use” (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than \$25,000 and

(2) December 17, 2012, for all other products subject to such rule.

NOTICE OF HEARING

COMMITTEE ON INDIAN AFFAIRS

Mr. AKAKA. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on May 24, 2012, in room SD-628 of the Dirksen Senate Office Building, at 2:15 p.m., to conduct a hearing entitled “Programs and Services for Native Veterans.”

Those wishing additional information may contact the Indian Affairs Committee at (202) 224-2251.

AUTHORITY FOR COMMITTEES TO MEET

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE, AND THE DISTRICT OF COLUMBIA

Ms. LANDRIEU. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs’ Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia be authorized to meet during the session of the Senate on May 21, 2012, at 2:30 p.m. to conduct a hearing entitled, “A National Security Crisis: Foreign Language Capabilities in the Federal Government.”

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. HARKIN. Mr. President, I ask unanimous consent that William McConagha and Kathleen Wise be granted the privilege of the floor for the duration of consideration of S. 3187, the Food and Drug Administration Safety and Innovation Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

NATIONAL PEDIATRIC STROKE AWARENESS MONTH

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 468, which was submitted earlier today by Senator BLUMENTHAL.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 468) expressing the sense of the Senate with respect to childhood stroke and recognizing May as “National Pediatric Stroke Awareness Month.”

There being no objection, the Senate proceeded to consider the resolution.

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motions to reconsider be laid upon the table, with no intervening action or debate, and any related statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The resolution (S. Res. 468) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 468

Whereas a stroke, also known as a cerebrovascular accident, is an acute neurologic injury that occurs when the blood supply to a part of the brain is interrupted by a clot in the artery or a burst of the artery;

Whereas a stroke is a medical emergency that can cause permanent neurologic damage or even death if not promptly diagnosed and treated;

Whereas stroke occurs in approximately 1 out of every 4,000 live births, and the risk of stroke from birth through age 18 is nearly 11 out of every 100,000 children per year;

Whereas an individual can have a stroke before birth;

Whereas stroke is among the top 10 causes of death for children in the United States;

Whereas between 20 percent and 40 percent of children who suffer a stroke die as a result;

Whereas stroke recurs in 20 percent of children who have experienced a stroke;

Whereas the death rate for children who experience a stroke before the age of 1 year is the highest out of all age groups;

Whereas the average time from onset of symptoms to diagnosis of stroke is 24 hours, putting many affected children outside the window of 3 hours for the most successful treatment;

Whereas between 50 and 85 percent of infants and children who have a pediatric stroke will have serious, permanent neurological disabilities, including paralysis, seizures, speech and vision problems, and attention, learning, and behavioral difficulties;

Whereas those disabilities may require ongoing physical therapy and surgeries;

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood have a considerable impact on children, families, and society;

Whereas very little is known about the cause, treatment, and prevention of pediatric stroke;

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for pediatric stroke; and

Whereas early diagnosis and treatment of pediatric stroke greatly improves the chances that the affected child will recover and not experience a recurrence: Now, therefore, be it

Resolved, That the Senate—

(1) acknowledges May as “National Pediatric Stroke Awareness Month”;

(2) urges the people of the United States to support the efforts, programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke;

(3) supports the work of the National Institutes of Health in pursuit of medical progress on the matter of pediatric stroke; and

(4) urges continued coordination and cooperation between government, researchers, families, and the public to improve treatments and prognoses for children who suffer strokes.

HONORING THE ENTREPRENEURIAL SPIRIT OF SMALL BUSINESS

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 469, submitted earlier today.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 469) honoring the entrepreneurial spirit of small business concerns in the United States during National Small Business Week, which begins on May 20, 2012.

There being no objection, the Senate proceeded to consider the resolution.

Ms. LANDRIEU. We have submitted a resolution, because it is Small Business Week, on behalf of myself and Senator SNOWE, Senator PRYOR, Senator LIEBERMAN, Senator ENZI, Senator KERRY, Senator BROWN, Senator CANTWELL, Senator AYOTTE, Senator RISCH, Senator CARDIN, and Senator HAGAN, a very good representation of our Small Business Committee and others that submitted a resolution this week, again, as we have done every year since 1953. We have done so every year since 1953 to recognize this week, or 1 week in the year, as Small Business Week. So that is what our resolution, which was submitted earlier today, does.

I hope Leaders MCCONNELL and REID will take up this resolution and pass it so we can honor the 28 million small businesses that exist today in America. We have been doing everything we can, and I am very proud, as the chairman of the Small Business Committee, that we have worked in a bipartisan fashion for the most part trying to give our businesses, first of all, the recognition that 9 out of 10 new jobs created were created by a small number, a very small number, of small businesses that are fast growing. They are the new job creators. These are the businesses that are going to be putting this recession behind us. These are the businesses that are innovating and adapting and changing and being more strategic and smarter, looking for those opportunities in all areas and in all geographic parts of our Nation.

Over the past few months my committee has held three very special roundtables to explore strategies, tools, and methods to strengthen what I like to call the ecosystem of entrepreneurship. Much like a rain forest or desert or much like the ocean itself, that is an environment where many creatures or organisms have to live and interact. The same is true of our financial ecosystem, the political ecosystem. Society itself is an ecosystem where small businesses have to function.

In order for them to be healthy, there have to be the right nutrients, if you will, present. So we have explored in our committee what—we know the United States does this well. We do it better than any country on Earth. That is one of the great strengths of

America; we foster that entrepreneurship, free but fair markets, well regulated, not too lightly, not too heavily. Sometimes we go a little overboard and we need to pull back. Sometimes we do not regulate enough and we need to step up. But that is what we have been exploring.

In fact, we have broken our roundtables into domains: Do our small businesses have enough access to capital? Do our small businesses truly have access to grow global markets? What did we learn this year? We learned that less than 12 percent of all small businesses in America export. With the market growing overseas and only the small percentage of the world market being now in the United States—we were at one time the biggest market, when China was closed, when communism was reigning in the Soviet Union, and the Arab world was in darkness. I mean the market was in the United States.

But that is no longer the case, as these countries and areas have emerged and created markets and opportunities of their own.

So one thing we learned is that the ecosystem needs to be stronger by helping small businesses to export. They do not have the back office or the expertise of 10 accountants and a Chinese specialist and a South American specialist. But we can, by being smart, help. Through the Commerce Department, the Small Business Administration, or maybe even through some of our research and development arms of some of our departments, we can be the back office for small businesses.

We are excited about what is happening there. So access to capital, access to global markets, access to counseling, mentoring, technical assistance and education. I have had so many small businesses come before our committee and say: You know, Senator, getting the loan from the bank was the first step. But if so-and-so had not shown up in my office from the Score Chapter or if I could not have reached out to my local university or my small business center there, I would never have been able to make it because they told me what to do to save me from making a fatal mistake and got me on my way or helped me to rethink my market during the recession.

How one lady put it before our committee, they helped her remarket her business so now it is growing faster than ever. I think also access to strategic partnerships is important. No man is an island. We do not accomplish anything by ourselves in the world. That is true of individuals, that is true of small businesses. So we asked ourselves: Who are the partners, strategic partners for small businesses? Cities are doing some creative things.

Madam President, you were a county executive. You know the things you did as a county executive. Your reputation is well known in that regard.

States can be strategic partners to their small businesses. We explored

those opportunities. Access to government contracting—you know, the Federal Government, state governments, and local governments are some of the biggest spenders and biggest businesses—if they were businesses, which they are not; there are clear differences—but if we were a business, the Federal Government would be the largest business in the world. It buys more goods and services than others. We do not have to do all of that just with the big businesses such as IBM, GE, ExxonMobil. We can contract with small businesses. It takes a little more time, takes a little more energy, takes a little bit different approach, but we most certainly can buy some of the things we need from the small business right down the street.

So we are shaping policies to do that. Senator CARDIN from Maryland has been particularly aggressive when it comes to contracting with minority and women-owned businesses, which make up a significant and growing area. It is very exiting as more women enter not just the workforce but decide they want their flexibility. They want to set their own hours. They want to be their own bosses. They want to establish businesses that allow them to also raise children at home, to be there when their kids need them. So they find that small businesses operating out of their homes are the answer to that dilemma. We want to give them access to government contracting when, of course, they are capable and provide the right price.

One of the big areas that we looked at is access to human capital. I think you probably heard, Madam President, many of our businesses saying: Why is it that we are bringing in some of the smartest people in the world, educating them at our universities, to where they are getting master's degrees and Ph.D.s in engineering, math, and science, and then we send them back to the country they came from so they can create businesses to compete against us? Why don't we extend visa privileges to these master's and Ph.D. candidates?

That is a good question, and we have bills to answer that. We also want to develop a skilled workforce in America. Access to human capital is what small businesses need to grow and to expand.

Finally, we need access to flexible regulation and smart tax policy. We are never going to live in a world where we do not pay taxes. It is just the nature of what we have to do to keep our government running and operating, with a government that serves the people—by the people, for the people.

But our taxes should not be too heavy, too burdensome, and our regulatory regime should not be either too light or too onerous. It should be just right. But it is hard to get that just-right approach. We are working at it every day. Senator SNOWE has been working on regulatory reform. Senator WARNER has been working very hard on regulatory reform—and other Members of this body.